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November 15, 2018

VIA CERTIFIED MAIL

Stephanie L. Parker
Clifton Parker
Restore Robotics LLC
5156 Belmore Ct.
Suwanee, GA 30024

Subject: Tampering with and Reprogramming *da Vinci*® Surgical System Instruments

Dear Ms. Parker and Mr. Parker,

We write on behalf of Intuitive Surgical, Inc. ("Intuitive"), a company that develops and distributes advanced robotic-assisted surgical platforms for minimally-invasive surgery. Our core products include the *da Vinci*® Surgical System (the "System") as well as the *EndoWrist*® instruments that attach to the System.

It has come to our attention that Restore Robotics LLC ("Restore Robotics") is engaging in the unauthorized manufacturing and marketing of a medical device [redacted] We also have concerns that the devices potentially being distributed are not being manufactured, or re-manufactured as the case may be, under a recognized quality management system applicable to medical devices. In addition, we believe that Restore Robotics has engaged in behavior that violates applicable laws and may give rise to civil liability. We write to you on behalf of Intuitive to demand that Restore Robotics immediately cease and desist from any and all improper behavior with regard to the *EndoWrist*® instruments, including but not limited to your actions described below.

[redacted]

INTUITIVE.

[redacted]

[redacted]

[redacted]

[redacted]

Factual Background

In accordance with its quality system, Intuitive engages in rigorous testing [redacted] Generally, and specifically with respect to the *EndoWrist*® instruments, that includes instrument reliability/projected life testing to confirm the maximum number of safe and effective clinical uses of a product prior to disposal. [redacted] With respect to many of the *EndoWrist*® instruments, Intuitive Surgical determined — [redacted] ten surgical procedures is the maximum number of safe and effective clinical uses prior to disposal. Accordingly, Intuitive placed a memory device inside such instruments that keeps track of the usage count and inhibits the instrument from functioning after ten uses.

We recently have become aware that you are offering Intuitive customers in the United States a type of "testing and repair" service for the *EndoWrist*® instruments. We understand that you are informing our customers that, rather than discarding the instruments after ten clinical uses, they can send you the instruments "that have only 1 use left" and you will clean and "utilize [y]our proprietary and patented process to restore the available uses to its original state."

Restore Robotics' Alleged Activities Violate U.S. Law

We have numerous concerns with the foregoing activities. First, it is unclear whether you or your service technicians have the requisite specifications by which to make the claim that the units are returned to their production equivalent qualification. Even assuming for argument that you have obtained these specifications, or Intuitive' s service manual, any modifications that reset or extend the number of uses of the device [redacted]. This change impacts the intended use of the device, exceeds the verified and validated testing [redacted], and thereby constitutes a major change to the device. This change could significantly affect the safety and effectiveness of the device [redacted]. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Your apparent false and misleading marketing practices and activities also may violate other U.S. federal and state laws and could expose Restore Robotics to significant financial liability. False

advertising statements regarding the safety and effectiveness of the modified *EndoWrist*® instruments are likely to deceive a substantial segment of your audience with respect to material characteristics of the instruments. The deception caused by such statements – and the attendant potential risk to patient health and safety through the use of modified *EndoWrist*® instruments – threaten to injure or have already injured Intuitive's business and reputation. Such deceptive practices also cause likelihood of confusion or of misunderstanding as to the modified *EndoWrist*® instruments, including but not limited to [redacted] affiliation with or approval by Intuitive, as well as key characteristics such as safety and effectiveness. In addition, the unauthorized use of Intuitive's marks in connection with advertisement of your "maintenance service" is likely to deceive or cause confusion about the source, affiliation, or quality and safety of the services provided and the modified *EndoWrist*® instruments. You also are liable to the extent your activities interfere with our customers' warranties.

Lastly and most critically, Restore Robotics' modification of the *EndoWrist*® instruments impacts the intended use of the device, exceeds the verified and validated testing performed by Intuitive [redacted] and therefore raises serious questions about the safety and effectiveness of the clinical use of such modified instruments in surgical procedures. For this reason, you could face significant financial liability from both practitioners and their patients in connection with your untested, unapproved modification of the *EndoWrist*® instruments.

Demand

Based on the foregoing apparent violations of U.S. law, Intuitive demands that Restore Robotics immediately cease and desist from:

a. marketing and offering a servicing process in the course of which the use counter of *EndoWrist*® instruments' memory device is manipulated and/or replaced to permit more than ten uses;

b. contacting Intuitive's customers to offer services related to Intuitive's products; and

c. [redacted]

Please confirm your compliance with these demands no later than December 14, 2018. If you allege that you [redacted] possess clinical proof that your service process returns the modified instruments to a "production equivalent qualification" and/or that additional use does not affect the safety or performance of the instruments, provide proof of the same no later than December 14, 2018.

We reserve all rights to take all appropriate action against you and to protect Intuitive's rights, products and reputation, including [redacted] pursuing appropriate civil remedies.

Very truly yours,

Romain Denis
VP, EU and US Regulatory Affairs

Kara Andersen Reiter
SVP, General Counsel & CCO